# Potential Tobacco Product Violations Form

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Office of Compliance and Enforcement, CTP
May 15, 2013

# Agenda

- Background
- Form 3779
- FDA Acknowledgment Letter
- FDA Follow-up
- Future
- Useful Links

# Background

- FDA's Center for Tobacco Products (CTP) is providing the public and other stakeholders with another option for reporting potential violations of the Tobacco Control Act and related regulations with the downloadable Potential Tobacco Product Violations Reporting form.
- By making it easier for everyone to report potential violations, FDA is able to better monitor compliance with the laws, help reduce the health burden of tobacco use on the American public, and protect the public health.

# Reporting Options

CTP provides the public and other stakeholders with various options to report potential violations of the Tobacco Control Act.

To report a potential violation, any interested party may:

- Call the Tobacco Call Center using CTP's toll-free number at 1-877-CTP-1373
- Email CTP at AskCTP@fda.hhs.gov
- Send a letter to FDA Center for Tobacco Products c/o Document Control Center, 9200 Corporate Boulevard, Rockville, MD 20850-3229
- Use CTP's new PDF Form, the Potential Tobacco Product Violations Reporting form (Form 3779)

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			FORM FDA 3779 (8/12)		Page 2 of 3	(continued on next page)		sor, and a person is not r	
DRM FDA 3779 (8/12)	Manufacturer Importer  Page 1 of 3	_ U	PSC Publishing Services (SEI) 441-0740 EF				Office of Chief Info	ormation Officer tion Act (PRA) Staff e, Room 400	
Who potentially violated? (choose all that apply)			istributor				2009 12 (3002)	alth and Human Services	5
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	Billboard	☐ Ir	iternet	vr group	))				age 0.25 hour per response
at apply)	Periodicals		oupons				OUR COMPLETED FO	ORM TO THE PRA STAF	FF ADDRESS BELOW.*
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Potential violation type choose all that apply)	Sales to minors Flavored cigarette sales	d	ending machine/self-service splay/direct access to cigarette or mokeless tobacco		rivate to the extent allowed by law. For more info				FEMAIL button. In the resulting of
				site ad	dress:			Print Form	Reset Form
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	Date and State Where Vio	lation Occurre	d					Report, Office of Complian	ace and Enforcement
To submit your r	eport, complete the form below:							ort to us in writing, along wi	th any attachments,
	nformation we receive from the pu arketed products and possible viola			stributo	rname		fill	ler to allow messages from ctp is is solved by adding our eme	ocompliance@fda.hhs.gov. In most o ail address to your address book.
WHAT is the po			1.011.11.201	ıd ph	ysical address of the potential violato	r, if known	No In order to receive a response, please configure your email spam		
	potential violation occur?								
WHEN did you	see the potential violation?								
Tell us:							Thore Hander		
FDA's Center for Tobacco Products.  WHO can report? - Any member of the public.							Phone Number		
Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.							State/Province/Region		
Directions:						Potential Tobacco F	Product Violations Re	eport	
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<b>Potential Tobacc</b>	o Product Violations	Report	(See page 3 for PRA Statement)	oter	ntial Tobacco Product Violations Repo	rt			
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

#### **Potential Tobacco Product Violations Report**

Form Approved: OMB No.: 0910-0716 Expiration Date: 07/31/2014 (See page 3 for PRA Statement)



#### **Directions:**

Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

WHO can report? - Any member of the public.

Tell us:

WHEN did you see the potential violation?

WHERE did the potential violation occur?

WHAT is the potential violation?

WHY report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

Date notential violation occurred (m					
Date potential violation occurred (mm/dd/yyyy)		I do not recall the date this potential violation occurred		State in which potential violation occurred	
Туре		Tobacco Brand			
Potential violation type	Sales to mino	s		Vending machine/self-service	
(choose all that apply)	Flavored cigar	ette sales		display/direct access to cigarette or smokeless tobacco	
	Advertising/pr	omotion/marketing		Sale of cigarettes in packs of less than 20	
	Free samples			Unsure	
Type of potentially	Newspaper			Price signage	
violative promotional materials <i>(choose all</i>	Magazine			Posters	
that apply)	Periodicals			Coupons	
	Billboard			Internet	
	Direct mail			Unsure	
	In-store adver	tisements			
				D. L.L.	
Who potentially violated?	Retailer			Distributor	
Who potentially violated? (choose all that apply)	Retailer  Manufacturer			Unsure	

#### Potential Tobacco Product Violations Report



**Description of potential violation** 

#### Name and physical address of the potential violator, if known

Retailer, manufacturer, importer, or distributor name

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Street Address

$\Rightarrow$	May we contact you if we need additional information?		No, I want my report to be anonymous. (Please note that if you submit this form by email, FDA will receive your email address. However, if you choose "no" FDA will not contact you.) Yes, FDA may contact me. (Please fill in contact information below.)
	Name		
	Affiliation (such as company, school,	or grou	p)

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Please email me to notify me that FDA got my complaint

\_ No □ Yes In order to receive a response, please configure your email spam/junk filter to allow messages from ctpcompliance@fda.hhs.gov. In most cases, this is solved by adding our email address to your address book.

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If you would rather submit your report to us in writing, along with any attachments, please do so at the following address:

Potential Tobacco Products Violation Report, Office of Compliance and Enforcement FDA Center for Tobacco Products
c/o Document Control Center
9200 Corporate Boulevard
Rockville, MD 20850-3229

To reach us by telephone, please call 1-877-CTP-1373, and select option 3. You may also email us at ctpcompliance@fda.hhs.gov.

Submit By Email

Print Form

Reset Form

An email message automatically will be produced when you click the SUBMIT BY EMAIL button. In the resulting email message, please don't forget to click the "Send" button or its equivalent when you are ready to send the email.

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# FDA Acknowledgment Letter



#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Center for Tobacco Products 9200 Corporate Boulevard Rockville, MD 20850-3229

Name of Individual Submitting Form Title of Individual Submitting Form Street Address City, State, Zip

Tracking Number: 1111111

Dear Individual Submitting Form:

This is in response to your letter received on May 15, 2013 in which you provided information regarding a regulated tobacco product. In your correspondence you described an alleged violation.

Thank you for providing this information to the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). We take such reports seriously, and we will evaluate this matter to determine what follow-up action, if any, is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem and the possible impact on the public health.

While FDA does not provide information regarding ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request once an investigation is closed. Written requests for information should reference the above tracking number and may be sent to the following address:

Food and Drug Administration
Division of Freedom of Information
Office of Shared Services
Office of Public Information and Library Services
12420 Parklawn Drive
ELEM-1029
Rockville. MD 20857

If you have any other information or additional questions, please contact CTP at AskCTP@fda.hhs.gov or 1-877-CTP-1373.

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# FDA Follow-Up

- The information provided on the form is reviewed by FDA's Office of Compliance and Enforcement (OCE) at CTP
- OCE evaluates the report and determines what follow-up action, if any, is appropriate
- Reports submitted by the public and stakeholders may be helpful in identifying possible violations of the Tobacco Control Act and related regulations that FDA enforces
- OCE independently collects evidence of a violation before it initiates any enforcement action

#### **Future**

#### In the future:

FDA plans to make a web-based form available

#### **Useful Links**

 The Potential Tobacco Product Violations Reporting form (Form 3779)

http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm

- The FDA's Center for Tobacco Products Homepage: www.fda.gov/tobaccoproducts
- The FDA's FOIA Division Homepage: <u>http://www.fda.gov/RegulatoryInformation/foi/default.htm</u>